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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 819,249	03 27 2001	Scott A. Waldman	IJU-2412	2090

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 09 26 2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/819,249

Applicant(s)

WALDMAN ET AL.

Examiner

ALEXANDER SPIEGLER

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event however may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b)

### Status

1) Responsive to communication(s) filed on 27 March 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-38 are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-28 (in part), drawn to methods of screening or diagnosing an individual suspected of having primary and/or metastatic stomach cancer, classified in class 435, subclass 4, for example.
  - II. Claims 1-24 (in part) and 29-32, drawn to methods of screening or diagnosing an individual suspected of having primary and/or metastatic esophageal cancer, classified in class 435, subclass 6, for example.
  - III. Claim 33 drawn to a kit comprising primers, classified in class 536, subclass 24.33, for example.
  - IV. Claim 33 drawn to a kit comprising antibodies, classified in class 530, subclass, 387.9, for example.
  - V. Claims 34-36 (in part), drawn to methods of treating primary and/or metastatic stomach cancer with an ST receptor ligand and an active agent, classified in class 514, subclass 1, for example.
  - VI. Claims 34-36 (in part), drawn to methods of treating primary and/or metastatic esophageal cancer with an ST receptor ligand and an active agent, classified in class 514, subclass 2, for example.
  - VII. Claims 37-38 (in part), drawn to methods of radioimaging primary and/or metastatic stomach cancer, classified in class 430, subclass 269, for example.

VIII. Claims 37-38 (in part), drawn to methods of radioimaging primary and/or metastatic esophageal cancer, classified in class 430, subclass 270.1, for example.

2. The inventions are distinct, each from the other because of the following reasons:

A) Inventions I, II, and V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are directed to methods, which have different method steps, starting materials, and goals. For example, Invention I is drawn to methods of screening or diagnosing an individual suspected of having primary and/or metastatic stomach cancer, whereas Invention II is directed to methods of screening or diagnosing an individual suspected of having esophageal cancer. Invention V is drawn to methods of treating primary and/or metastatic stomach cancer with an ST receptor ligand and an active agent, whereas Invention VI is drawn to methods of treating primary and/or metastatic esophageal cancer with an ST receptor ligand and an active agent. Invention VII is drawn to drawn to methods of radioimaging primary and/or metastatic stomach cancer, whereas Invention VIII is drawn to drawn to methods of radioimaging primary and/or metastatic esophageal cancer.

B) Inventions (I and II) and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of Group I can be practiced with a materially

C) Inventions (I and II) and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of Group I can be practiced with a materially different product such as PCR primers or a nucleic acid probe.

D) Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a kit comprising primers (i.e. Invention III) and a kit comprising antibodies (i.e. Invention IV), which are two different chemical entities having differing biochemical structures, modes of operation, functions, and effects. Invention III would require searching in areas unrelated to antibodies, and as such, would require an undue burden on the examiner if not restricted.

E) Inventions (III and IV) and V-VIII and are separate and distinct as the kit of Inventions III and IV are not used in the methods of Inventions V-VIII. As such, the Inventions would require search in separate and non-overlapping areas, imposing an undue search burden upon the examiner if not restricted.

3. Because these inventions are distinct for the reasons given above and have acquired a

1 by their different classification and recognized divergent subject matter.

extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

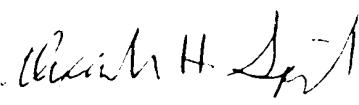
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

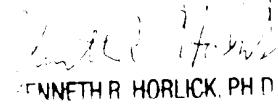
***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Alexander H. Spiegler  
September 24, 2002

  
KENNETH R. HORLICK, PH.D.  
JULY 2002